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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,017	11/16/2000	Andre Chouluka	02356.0077-01	6042

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EXAMINER

EPFS FORD, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

**Office Action Summary****Application No.**

09/713,017

**Applicant(s)**

CHOULIKA ET AL.

**Examiner**

Janet L. Epps-Ford, Ph.D.

**Art Unit**

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,25 and 28-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 39 is/are allowed.
- 6) ☒ Claim(s) 1,25,28-38 and 40-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed 12-05-03, with respect to the rejection(s) of claim(s) 1, 25, 28-38, and 40-45 under 35 USC § 112 have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, new ground(s) of rejection under 35 USC 112, 1<sup>st</sup> paragraph and under 35 USC 102(b) are set forth below.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 25, 28-38, and 40-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (Written Description).

4. The instant claims are drawn to nucleic acid molecules comprising a "recognition sequence", or a sequence comprising a "recognition sequence" and further encoding a "recombinase." Moreover, claims 1, 25, 28, 39, 37-38, 40, and 42-45 do not recite that the "recognition sequence" is a "recombinase" recognition site. Therefore, the "recognition sequences" recited in these claims may encompass nucleic acid sequences that are recognized by other molecules including any protein that recognizes a nucleic acid sequence (including Splicing Factors (*that recognize splice sites*) Restriction Enzymes, transcription factors, etc.),

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other cis-acting nucleic acid sequences, sugars, lipids, and etc. As stated above, the specification as filed has not provided any guidance that would allow the skilled artisan to predict the structures of the full scope of “recognition sequences” encompassed by the instant claims. Additionally, the specification as filed does not describe the full scope of nucleic acid sequences encoding the full scope of recombinases encompassed by the instant claims.

The specification does describe the loxP “recognition sequence,” set forth on page 12, lines 6-7. However, there is no evidence that this limited information can be used to predict the structures of the full scope of nucleic acid sequences that would be useful as “recognition sequences” or the nucleic acid sequences encoding their corresponding recombinases as set forth in the instant claims. Moreover, it is noted that the instant claims are not limited to those loxP recognition sequences set forth in the specification as filed.

See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, “Written Description” Requirement. These guidelines state: “[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was “ready for patenting” such as by the disclosure of drawings or structural chemical

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formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention.”

Moreover, see MPEP § 2163, which states “A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” In the instant case, as set forth above, the instant claims are drawn to a broad scope of recognition sequences and nucleic acid sequence encoding a recombinase that are not specifically described by structure. The ordinary skilled artisan would have to resort to further experimentation to identify the full scope of nucleic acid sequences encompassed by the instant claims. Therefore, the full scope of the claimed invention was not reduced to practice or “ready for patenting,” at the time of filing of the instant invention.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 25, 28, 37, 40, and 44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilboa et al. (WO 89/11539 A1).

To the extent that the “recognition sequences” encompassed by the instant claims read on sequences that may be recognized by Restriction Enzymes, or Splicing factors, the following prior art is applied.

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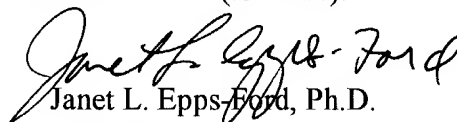
Gilboa et al. describe the double copy retroviral vector, which comprises an insertion of the ADA gene sequence into the U3 region of a 3' LTR, see for example Figure 4, and page 13, lines 12-29. Notice also that the ADA gene comprises a BAM HI restriction enzyme recognition site (see Figure 5B). Gilboa et al. is considered to anticipate the instant invention.

*Allowable Subject Matter*

7. Claim 39 is allowable over the prior art of searched.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Janet L. Epps-Ford, Ph.D.  
Examiner  
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JLE